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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,724	12/08/2003	Antonius Arnoldus Christiaan Jacobs	I 1999.452 US C1	5481

31846 7590 06/03/2010

Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
06/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com
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Office Action Summary	Application No.	Applicant(s)	
	10/731,724	JACOBS ET AL.	
	Examiner	Art Unit	
	JD SCHULTZ	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,13-16,21 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,13-16,21 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed February 23, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed January 21, 2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application contains claims 9, 13-16, 21, and 25-28, which are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 9, 13, 21, 22, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al. (U. S. Patent Number 6,120,775). This rejection is repeated for reasons of record as set forth in the action mailed January 21, 2010 and reproduced below.

The claimed invention is drawn to a method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine, wherein the method comprises administering submucosally the vaccine, whereby the amount of adverse reactions at the injection site is reduced, the live bacterial vaccine comprises bacteria that cause abscess formation when administered intramuscularly, and the reduction of the amount of adverse reactions is measured by the amount or size of abscesses at the mucosal injection site compared to an intramuscular injection site, wherein the vaccine may be administered to a horse.

Jacobs et al. teach a method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine, wherein the method comprises administering submucosally the vaccine, whereby the amount of adverse reactions at the injection site is reduced, the live bacterial vaccine comprises bacteria that cause abscess

formation when administered intramuscularly, and the reduction of the amount of adverse reactions is measured by the amount or size of abscesses at the mucosal injection site compared to an intramuscular injection site, wherein the vaccine is administered to a horse (see column 3 for example).

At least claim 1 of the instant application is directed to the same invention as at least claim 1 of the commonly assigned patent to Jacobs et al. (U. S. Patent Number 6,120,775). The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Response to Request for Reconsideration

Applicants traverse, asserting that the scope of the claims in the '775 patent is limited to protecting a horse against *Streptococcus equi* infection, while the present claims are directed to reducing adverse reactions in a mammal at the injection site of an attenuated bacterial vaccine. This is not adopted. The claim 1 of the '775 patent recites

> "1. A method for protecting a horse against Streptococcus equi infection, comprising administering a vaccine comprising a live attenuated bacterium of the species *Streptococcus equi* and pharmaceutically acceptable carrier, wherein said vaccine is administered submucosally or labially."

The instant claim 9 recites:

> 9. (Previously presented) A method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine, wherein: the method comprises administering submucosally the vaccine, whereby the amount of adverse reactions at the injection site is reduced, the live bacterial vaccine comprises bacteria that cause abscess formation when administered intramuscularly, and the reduction of the amount of adverse reactions is measured by the amount or size of abscesses at the mucosal injection site compared to an intramuscular injection site.

Patented claim 1 is drawn to submucosal delivery of a species of live attenuated bacterium (*S. equi*) to a species of mammal (horse). The instant claim 9 requires the same, but does not recite the species. Since all manipulative steps, structures and compounds of the prior art claim anticipate the elements of the instant claim 9, it is presumed that applicants intend to argue that the difference of the instant claim 9 lies in its functional language, directed to reducing adverse reactions and bacterial abscess formation upon intramuscular injection. However, these elements are considered to be inherent to patented claim 1, and would flow naturally from its practice. There is no additional method step or compound necessary to reduce adverse reactions or decrease bacterial abscess formation beyond those steps recited in patented claim 1. In point of fact, example 1 of the instant application teaches administration of live attenuated *S. equi* bacterium submucosally. This example teaches that the bacterium causes abscess formation when administered intramuscularly, which is absent when performed submucosally. Thus, in addition to patented claim 1 anticipating all manipulative steps, structures and compounds of the instant claim 9, example 1 of the prior art patent also exemplifies that all functional limitations of instant claim 9 are inherent to patented claim 1. The rejection is maintained therefore.

Applicants also argue that Jacobs '775 is NOT available as a reference. Applicants assert that the present application is a continuing application based on U.S. Application Number 09/492,206 (now US Patent 6,682,745), which is a continuation-in-part of USSN 09/123,735 (now US Patent 6,120,775). Applicants have submitted a copy of an amendment filed November 13, 2000 in parent application USSN 09/492,206, filed January 27, 2000, reciting that the application was "a continuation-in-part of USSN 09/123,735, filed July 28,1998, now U.S. Patent No. 6,120,775, issued September 19, 2000."

This argument is not convincing. The rejection is maintained, since the instant application claims priority only to U.S. Application Number 09/492,206, filed January 27, 2000, and foreign priority to 99200202.2, filed January 26, 1999. The instant application does NOT claim priority to U.S. Application Number 09/123,735 (US Patent 6,120,775, hereinafter the '775 patent). Since this application is by another, i.e. it does not list Danny Goovaerts as an inventor as is the case instantly, the rejection under 35 U.S.C. § 102(e) is considered proper and is maintained. 35 U.S.C. 120 states the following:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application **and if it contains or is amended to contain a specific reference to the earlier filed application.** No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

The instant application does not contain a specific reference to the '775 Patent. Thus, it is irrelevant what U.S. Application Number 09/492,206 (parent of the instant application) claims

priority to, since there is no reference in the instant application to the '775 patent as required by 35 U.S.C. 120. Jacobs '775 was filed on July 28, 1998, which is clearly before the earliest claimed filing date of the instant application. The rejection is maintained therefore.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 13-16, 21, 22, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Claims 9, 13-16, 21, 22, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (supra) as applied to claims 9, 13, 21, 22, and 25 above. This rejection is repeated for reasons of record as set forth in the action mailed January 21, 2010 and reproduced below.

The invention is as described above, wherein the mammal may be a ruminant, or a pig, or a dog.

Jacobs et al. does not teach that his method of vaccination should be used in a ruminant, or a pig, or a dog.

It would have been obvious to one of ordinary skill in the art to take the method of vaccination disclosed by Jacobs et al. and apply it to other mammals such as a ruminant, or a pig, or a dog. One of ordinary skill would have been motivated to do so since mechanisms of

immunity are highly conserved amongst closely related mammals, and since there would be a financial incentive to use a known successful method of vaccination that has been successfully demonstrated in one species and apply it to others. Accordingly, the invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Request for Reconsideration

Applicants argue that Jacobs '775 was not available as prior art for the same reasons provided in arguments traversing the rejection above under 35 U.S.C. § 102(e). Since Jacobs '775 is considered valid for the reasons set forth above, the rejection is maintained.

Perfection of Foreign Priority

Applicants have requested transfer of the certified copy of EP 99200202.2 from the parent application serial number 09/492,206 to the instant application. The examiner is not aware of any authority by which such a transfer may take place. It is requested that applicants provide such justification by way of M.P.E.P. reference in order to complete the claim for foreign priority.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JD SCHULTZ whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JD SCHULTZ/
Primary Examiner, Art Unit 1633